



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/637,190	08/11/2000	Mien-chic Hung	12005-002001	8780

7590

04/09/2002

Y Rocky Tsao
Fish & Richardson PC
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 04/09/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/637,190

Applicant(s)
Hung et al

Examiner
Karen Canella

Art Unit
1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-20 is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 11 and 16 have been amended. Claims 1-20 are under consideration.

Claim Rejections Withdrawn

3. The rejection of claims 11-20 under 35 U.S.C. 112, first paragraph is withdrawn in light of applicants amendments to claims 11 and 16.
4. The rejection of claims 1-10 under 35 U.S.C. 102(a) as being anticipated by Xia et al (Oncogene, 2000, Vol. 19, pp. 2398-2403) is withdrawn in light of the Declaration provided under 37 C.F.R. 1.132.

Claim Rejections Maintained

5. The rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Sager et al (USP 5,470,970) in view of Ding et al (Proceedings of the American Association of Cancer Research, 1996, Vol. 37, pp. A627) and either Gregory et al (USP 5,932,210) or Hung et al (USP 6,197,754), is maintained for reasons of record. Applicant argues that the combination of references does not constitute a prediction method. This has been considered but not found persuasive. Sager et al teach that maspin functions as a tumor suppressor gene in breast cancer. Ding et al teach that maspin gene expression is found in breast epithelial cells and in squamous cell carcinomas of the esophagus and tongue. Either Gregory et al (column 21, lines 64-67) or Hung et al teach that the presence of a tumor suppressor gene product (column 12, lines 12-14) is correlated with increased survival time. Thus the prior art teaches that maspin is a tumor suppressor gene found in squamous cell carcinoma, and the presence of tumor suppressor genes is indicative of increased survival time. Thus one of skill in the art would conclude that the expression of the maspin tumor suppressor gene in a sample of squamous cell carcinoma would


indicate a relatively high probability of survival in a patient in contrast to samples exhibiting a lack of expression of said gene.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


KAREN A. CANELLA
PATENT EXAMINER
TECHNICAL CENTER

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

April 8, 2002